CareSource

PHARMACY POLICY STATEMENT **Indiana Medicaid**	
DRUG NAME	Tavalisse (fostamatinib disodium hexahydrate)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) Alternative preferred product includes eltrombopag QUANTITY LIMIT— 60 tabs per 30 days
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Tavalisse (fostamatinib disodium hexahydrate) is a **non-preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

CHRONIC IMMUNE THROMBOCYTOPENIA (ITP)

For **initial** authorization:

1. Member is 18 years of age or older with diagnosis of chronic ITP for at least 3 months; AND
2. Medication must be prescribed by or in consultation with a hematologist; AND
3. Member had an inadequate response, intolerance, or contraindication to documented prior therapy with ONE of the following treatments:
   a) Corticosteroids (prednisone, prednisolone, methylprednisolone, and dexamethasone);
   b) Immunoglobulins;
   c) Splenectomy; AND
4. Member has tried and failed treatment with eltrombopag or romiplostim (Nplate); AND
5. Member's platelet count is < 35,000/µL or there is documentation that the member has experienced significant bleeding at a higher platelet count; AND
6. Member does not have ANY of the following:
   a) Clinical diagnosis of autoimmune hemolytic anemia;
   b) Uncontrolled or poorly controlled hypertension;
   c) History of coagulopathy including prothrombotic conditions.
7. **Dosage allowed:** Initiate Tavalisse at 100 mg orally twice daily with or without food. After 4 weeks, increase to 150 mg twice daily, if needed, to achieve platelet counts of at least 50 x 10^9/L as necessary to reduce the risk of bleeding.

Note: Discontinue Tavalisse after 12 weeks of treatment if the platelet count does not increase to a level sufficient to avoid clinically important bleeding.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:

1. Member's platelet count of at least 50 x 10^9/L was achieved and documented in chart notes; AND
2. Monthly CBCs (including platelet counts), monthly liver function tests (e.g., ALT, AST, and bilirubin), and monthly blood pressure measurements submitted with chart notes; AND

3. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 6 months.

CareSource considers Tavalisse (fostamatinib disodium hexahydrate) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Thrombocytopenia due to Myelodysplastic syndrome (MDS)

DATE	ACTION/DESCRIPTION
08/31/2018	New policy for Tavalisse created.

References:

1. Tavalisse [package insert]. South San Francisco, CA: Rigel Pharmaceuticals, Inc., April, 2018.
2. ClinicalTrials.gov. Identifier: NCT02076399. A Efficacy and Safety Study of R935788 in the Treatment of Persistent/Chronic Immune Thrombocytopenic Purpura (ITP) (FIT). Available at: https://clinicaltrials.gov/ct2/show/NCT02076399?term=NCT02076399&rank=1.
3. ClinicalTrials.gov. Identifier: NCT NCT02076412. A Efficacy and Safety Study of Fostamatinib in the Treatment of Persistent/Chronic Immune Thrombocytopenic Purpura (ITP) (FIT). Available at: https://clinicaltrials.gov/ct2/show/NCT02076412?term=02076412&rank=1.
4. ClinicalTrials.gov. Identifier: NCT 02077192. Open Label Study of R788 in the Treatment of Persistent/Chronic Immune Thrombocytopenic Purpura (ITP). Available at: https://clinicaltrials.gov/ct2/show/NCT02077192?term=NCT+02077192&rank=1.
5. Diagnosis and treatment of idiopathic thrombocytopenic purpura: recommendations of the American Society of Hematology. Ann Intern Med. 1997 Feb 15;126(4):319-26.
6. George JN, et al. Immune thrombocytopenia (ITP) in adults: Initial treatment and prognosis. In: UpToDate. Waltham, MA: UpToDate; 2018.
7. George JN, et al. Immune thrombocytopenia (ITP) in adults: Second-line and subsequent therapies. In: UpToDate. Waltham, MA: UpToDate; 2018.
8. NCCN Guidelines. Myelodysplastic Syndromes. V.1.2019.

Effective date: 01/01/2019
Revised date: 08/31/2018